

PATENT
Attorney Docket No. 101.0093-01000
Customer No. 22882

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
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In re Application of:) Confirmation No.: 6670
Gary K. Michelson)
Serial No.: 10/675,820) Group Art Unit: 3775
Filed: September 30, 2003) Examiner: James L. Swiger III
For: DYNAMIC GUARD)

Mail Stop APPEAL BRIEF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPEAL BRIEF

Real Party In Interest

The real party in interest is Warsaw Orthopedic, Inc. ("Appellant"), the assignee of record, which is a subsidiary of Medtronic, Inc.

Related Appeals and Interferences

There are no appeals or interferences pending which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims

Claims 1-30 (including independent claim 1) are currently pending, and have been finally rejected in the Final Office Action of July 25, 2008 ("Final Office Action") and are being appealed.

Claims 2-30 are dependent from independent claim 1, or claims dependent therefrom.

Claims 31-51 have been cancelled.

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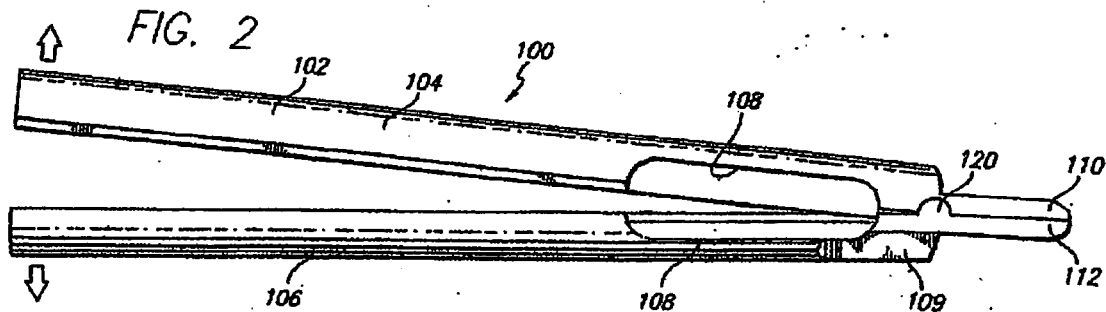
Status of Amendments

An Amendment is being filed concurrently herewith to correct typographical/clerical errors in independent claim 1 and dependent claim 12. No other amendments have been made to the claims subsequent to the Final Office Action.

Summary of Claimed Subject Matter

Independent Claim 1.

The claimed invention, in one preferred embodiment, is generally drawn to a guard (100) for use in human spinal surgery. The guard (100) has a body (102), as shown in Fig. 14, having a leading end and an opposite trailing end in relation to a human spine. As shown in Figs. 2 (included below) and 4, the body (102) has a first portion (104) and a second portion (106) having a pivotal relationship to one another between an open position and a closed position.



The first and second portions (104) and (106), as shown in Fig. 15, have at least in part opposed interior arcuate portions, and the first and second portions (104) and (106) define an opening for providing a protected pathway to adjacent vertebral bodies and a disc space therebetween. As shown in Fig. 2 (included above), the first and second portions (104) and (106) are pivotal about an axis that passes through at least a portion of the pathway. The opposed interior arcuate portions are parallel to one another when the body (102) is in the closed position (Fig. 4), and the opposed arcuate portions are angled to one another when the body (102) is in the open position (Fig. 2).

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The opening defined by the first and second portions (104) and (106) is generally circular (Fig. 6) when the guard is in the closed position. As shown in Figs. 16 and 18, the opposed interior arcuate portions are adapted to guide there through a surgical instrument. The body (102), as shown in Fig. 6, has an exterior surface (116) that has opposed upper and lower surfaces, and opposed side surfaces. The opposed upper and lower surfaces, and the opposed side surfaces are at least in part arcuate, and, as shown in Fig. 15, the opposed upper and lower surfaces are oriented toward the adjacent vertebral bodies. Finally, as shown in Fig. 6, the first and second portions (104) and (106) of the body (102) form a tube when in the closed position.

Grounds of Rejection to be Reviewed on Appeal

- I. Claims 1-28 (including independent claim 1) are rejected under 35 U.S.C. § 103(a) based on U.S. Patent Publication No. 2003/0135220 to Cauthen ("Cauthen") in view of U.S. Patent No. 5,846,249 to Thompson ("Thompson").
- II. Claim 29 is rejected under 35 U.S.C. § 103(a) based on Cauthen in view of Thompson and further in view of U.S. Patent Publication No. 2003/0023209 to Gruskin et al. ("Gruskin").
- III. Claim 30 is rejected under 35 U.S.C. § 103(a) based on Cauthen in view of Thompson and further in view of U.S. Patent Publication No. 2003/0229401 to Mansouri et al. ("Mansouri").

Argument

Appellant submits the following arguments for consideration by the Board of Patent Appeals and Interferences:

I. Rejection of claims 1-28 (including independent claim 1) under 35 U.S.C. § 103(a) as being unpatentable over the combination of Cauthen and Thompson.

In rejecting independent claim 1 based on the combination of Cauthen and Thompson, the Examiner indicates that Cauthen discloses "the claimed invention except for more specifically an axis that passes through at least a portion of the pathway, allowing the two portions to articulate and distract vertebrae," but that

"Thompson discloses this feature, having two curved halves articulate about an axis that passes through at least a portion of the passageway (see joints via 123)." (Final Office Action, first paragraph of page 4.) According to the Examiner, "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Cauthen having at least the axis that passes through at least a portion of the pathway in view of Thompson to better use the device to distract the vertebrae." (Final Office Action, first paragraph of page 4.) However, contrary to the Examiner's contentions, Appellant submits that the rejection of independent claim 1 under 35 U.S.C. § 103(a) based on a combination of Cauthen and Thompson cannot be maintained.

In KSR International Co. v. Teleflex Inc. et al., the Supreme Court reaffirmed the framework for governing obviousness under 35 U.S.C. § 103(a) as set forth in Graham et al. v. John Deere Co. of Kansas City et al., 383 U.S. 1, 148 U.S.P.Q. 459 (1966). (See KSR v. Teleflex, 127 S.Ct. 1727 (2007).) Under Graham v. John Deere, the question of obviousness is resolved on the basis of factual determinations including (1) the scope and content of the prior art, (2) the differences between the claimed invention and the prior art, (3) the level of ordinary skill in the pertinent art, and (4) where in evidence, so-called secondary considerations. (See Graham v. John Deere, at 17-18, 148 U.S.P.Q. at 467.) Even under Graham v. John Deere, however, prior art that is non-analogous to the claimed invention, references that teach away from a combination thereof, and/or a combination of references that produces an inoperable result support a finding of nonobviousness. As discussed below, Appellant submits that Thompson is non-analogous art to the claimed invention, Cauthen and Thompson teach away from one another, and the combination of Cauthen and Thompson is inoperable in response to the Examiner's rejection of independent claim 1.

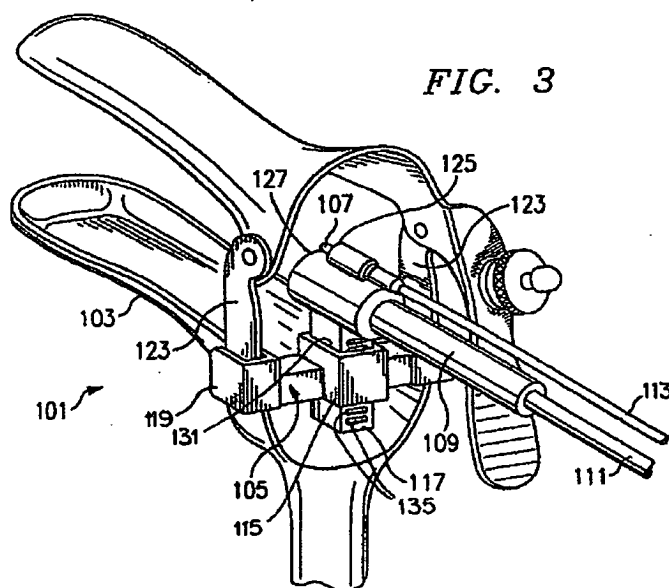
A. Thompson is non-analogous art to the claimed invention of independent claim 1.

Thompson is directed to a video gynecological examination apparatus used in conjunction with conventional speculums for dilating a patient's vagina. According to the Examiner, Thompson discloses the feature of "having two curved halves articulate

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about an axis that passes through at least a portion of the passageway (see joints via 123)." As such, in rejecting independent claim 1, the Examiner relies on an instrument, one of the conventional speculums of Thompson, that is used in dilating soft tissue of a patient.

As shown in Fig. 3 of Thompson (Included below), the element labeled with the number 123 properly refers to arms formed on either side of a speculum 103.



The arms 123 space apart an upper portion and a lower portion of the speculum 103, and are hingedly connected to the upper portion. The arms 123 and associated hinged connections are positioned at the trailing end of the speculum 103, and the leading end of the speculum 103 (including most of the upper and lower portions) are inserted into the patient's vagina. The upper portion and the lower portion of the speculum 103 are used in dilating soft tissue of the patient's vagina.

According to MPEP § 2141.01, "a reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole." Hence, the pertinence of a reference is determined by if the reference can be logically associated with the claimed

invention. Furthermore, the Federal Circuit (albeit in a non-precedential opinion) recently in Andersen Corp. v. Pella Corp., provided guidance regarding the evaluation of non-analogous art under 35 U.S.C. § 103(a). (Andersen Corp. v Pella Corp., ___ Fed. Appx. ___, 2008 U.S. App. LEXIS 24087 (Fed. Cir. Nov. 19, 2008).) In Andersen Corp., the Federal Circuit considered whether an insect screen was obvious in view of a mesh used for electromagnetic shielding manufactured by TWP. TWP manufactured both the electromagnetic-shielding mesh used in the obviousness rejection and the insect screen.

While declining to decide the issue, the Federal Circuit found that a genuine issue of fact was raised "as to whether the electromagnetic-shielding mesh would have been part of the field of invention searched by an insect screen designer and whether such an alternative use would have been obvious." (Id. at 12.) According to the Federal Circuit, "[t]he fact that TWP's use for the mesh was electromagnetic shielding and that TWP, a company that manufactures insect screens, did not employ this particular mesh as an insect screen suggests that common sense and the nature of the problem to be solved might not have made it obvious to an insect screen designer to try using the mesh as an insect screen." (Id.)

Appellant submits that the speculum 103 of Thompson is not logically associated with the claimed invention. The speculum 103 is inserted into a patient's vagina to facilitate dilation of soft tissue. However, the human spinal surgery involves instruments, such as the guard of independent claim 1, that contact bone. Therefore, Applicant submits that the speculum 103 of Thompson is not even remotely related to a guard for use in human spinal surgery as claimed in Independent claim 1. As such, there is no logical association between the claimed invention and the speculum 103. Therefore, under the guidance of MPEP § 2141.01, Thompson is non-analogous art to the claimed invention.

Furthermore, speculums, such as the speculum 103 of Thompson, are not employed in human spinal surgery. Human spinal surgery, as discussed above, involves the use of instruments that contact bone. Therefore, Appellant submits that

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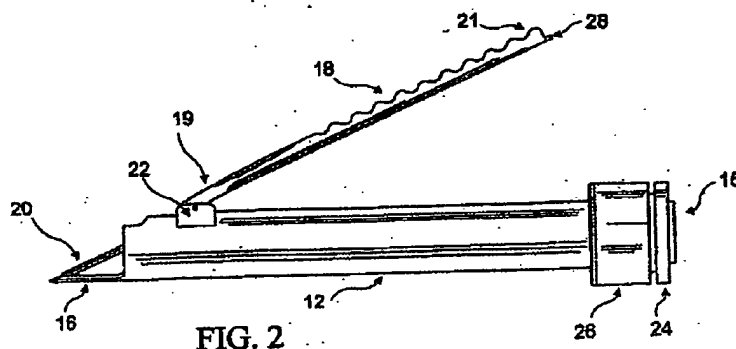
the use of speculums in dilating soft tissue of a patient's vagina would preclude consideration thereof for use in human spinal surgery. Thus, common sense and the nature of the problem to be solved would not have made it obvious to a designer of guards for use in human spinal surgery to try using instruments for dilating a patient's vagina. Therefore, using the guidance of the Federal Circuit in Anderson Corp., Thompson is again non-analogous art to the claimed invention.

Given that Thompson is non-analogous art, Appellant submits that Thompson cannot be used as the basis for an obviousness rejection of independent claim 1. Accordingly, Appellant submits that independent claim 1 is patentable over the Examiner's rejection under 35 U.S.C. § 103(a) based on Cauthen and Thompson.

B. Cauthen and Thompson teach away from one another.

References that teach away from the combination thereof support a finding of nonobviousness. KSR v. Teleflex explains “that when the prior art teaches away from a combination, that combination is more likely to be nonobvious.” (In re Icon Health and Fitness, Inc., 496 F.3d 1374, 1381 (Fed. Cir. 2007) citing KSR v. Teleflex, 127 S.Ct. at 1739-40.) Accordingly, references that teach away from the combination thereof, and hence the claimed invention, can be determinative of a finding of nonobviousness.

Cauthen teaches two instruments (10), one of Figs. 1 and 2 and another of Figs. 13 and 14. The insertion instrument (10) of Figs. 1 and 2 (included below) includes a hollow body (12), and a handle (18) with a guide (20) extending therefrom pivotal about an articulating hinge (22).



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The articulating hinge (22) has a pivot axis disposed on the exterior of the hollow body (12), and is positioned adjacent the leading end of the insertion instrument (10) of Figs. 1 and 2.

The insertion instrument (10) of Figs. 13 and 14 (included below) includes a hollow body (12), a handle (18) with an associated guide (20), and a handle (37) with an associated guide (35) pivotal about articulating hinges (22) and (36), respectively.

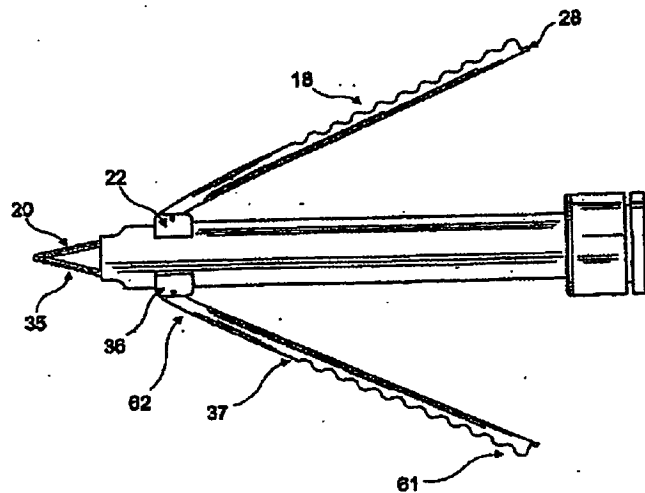


FIG. 14

The articulating hinges (22) and (36) also have pivot axes disposed on the exterior of the hollow body, and positioned adjacent the leading end of the insertion instrument (10) of Figs. 13 and 14.

Accordingly, contrary to the teachings of Thompson, Cauthen teaches that the articulating hinge (22) of Figs. 1 and 2 and the articulating hinges (22) and (36) of Figs. 13 and 14 are positioned adjacent the leading ends of the insertion instruments (10). Furthermore, contrary to the teachings of Thompson where the pivot axis of the speculum 103 is located between the upper and lower portions, the pivot axes of the articulating hinge (22) of Figs. 1 and 2 and the articulating hinges (22) and (36) of Figs.

13 and 14 are disposed on the exterior of the hollow bodies (12). Finally, while the pivot axes of Cauthen are disposed on the exterior of the hollow bodies (12), the handle (18) and the handles (18) and (37) of Cauthen, contrary to the teachings of Thompson (where the upper portion and the lower portion are spaced apart from one another), are not offset from the hollow bodies (12). Given these contrary teachings, and the inherent difficulty in combining references having contrary teachings, Appellant submits that Cauthen and Thompson teach away from one another.

C. The combination of Cauthen and Thompson is inoperable.

"If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." (MPEP § 2143.01 Section V, *citing* In re Gordon, 733 F.2d 900 (Fed. Cir. 1984).) If, despite the inherent difficulty in combining references having contrary teachings, Cauthen and Thompson were combined, Appellant submits that the resulting combination would be inoperable, and hence, unsatisfactory for its intended purpose.

As shown in Fig. 3 of Thompson, the pivot axis of the speculum 103 is located between the upper portion and the lower portion thereof. However, if such a teaching were applied to Cauthen, Appellant submits that the resulting combination is inoperable. For example, if the instrument (10) of Fig. 2 of Cauthen were so modified, the hinge (22) (and its associated pivot axis) would be moved to a position in the passage of the hollow body (12). However, because of the new position of the hinge (22) in the passage, the operation of the instrument (10) would be prohibited. That is, the passage through the hollow body (12) would be interrupted, and therefore, instruments could not be inserted therethrough. Accordingly, Appellant submits that modifying Cauthen with the teachings of Thompson would render the resulting combination unsatisfactory for its intended purpose.

Because Thompson is non-analogous art to the claimed invention, Cauthen and Thompson teach away from one another, and the combination of Cauthen and Thompson produces an inoperable result, the Examiner's rejection of independent

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claim 1 under 35 U.S.C. § 103(a) based on Cauthen and Thompson cannot be maintained. As such, Appellant submits that independent claim 1 is patentable over the Examiner's rejection under 35 U.S.C. § 103(a), and that dependent claims 2-28 are patentable at least due to their dependency from an allowable independent claim.

II. Rejection of claim 29 under 35 U.S.C. § 103(a) as being unpatentable over the combination of Cauthen, Thompson, and Gruskin.

Appellant submits that, because independent claim 1 is allowable, the rejection of claim 29 under 35 U.S.C. § 103(a) is moot. Dependent claim 29, dependent from claims depending from independent claim 1, is patentable at least due to its dependency from an allowable independent claim.

III. Rejection of claim 30 under 35 U.S.C. § 103(a) as being unpatentable over the combination of Cauthen, Thompson, and Mansouri.

Appellant submits that, because independent claim 1 is allowable, the rejection of claim 30 under 35 U.S.C. § 103(a) is moot. Dependent claim 30, dependent from claims depending from independent claim 1, is patentable at least due to its dependency from an allowable independent claim.

VI. Conclusion

Appellant submits that independent claim 1 is patentable and that dependent claims 2-30 dependent from independent claim 1, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim. Therefore, Appellant respectfully requests the Board reverse the Examiner's rejections and allow claims 1-30.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith,

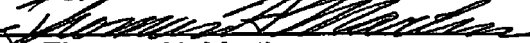
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including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,

MARTIN & FERRARO, LLP

Dated: January 23, 2009

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CLAIMS APPENDIX

1. A guard for use in human spinal surgery, comprising:
a body having a leading end and an opposite trailing end, said body having a first portion and a second portion in pivotal relationship to one another between an open position and a closed position, said first and second portions having at least in part opposed interior arcuate portions, respectively, said first and second portions defining an opening for providing a protected pathway to adjacent vertebral bodies and a disc space therebetween, said first and second portions being pivotal about an axis that passes through at least a portion of the pathway, said opposed interior arcuate portions of said first and second portions of said body being parallel to one another when said body is in the closed position, said opposed interior arcuate portions of said first and second portions of said body being angled to one another when said body is in the open position, said opening defined by said first and second portions of said body being generally circular when said body is in the closed position, said opposed interior arcuate portions being adapted to guide there through a surgical instrument, said body having an exterior surface that has opposed upper and lower surfaces oriented toward the adjacent vertebral bodies, respectively, said upper and lower surfaces being at least in part arcuate, said exterior surface of said body having opposed side surfaces, said side surfaces being at least in part arcuate, said first and second portions of said body when in the closed position forming a tube.
2. The guard of claim 1, wherein said opening defined by said first and second portions of said body is generally oval when in the open position.
3. The guard of claim 1, wherein said opening defined by said first and second portions of said body is generally elliptical when in the open position.
4. The guard of claim 1, wherein at least a portion of said upper and lower surfaces of said exterior surface are parallel to one another when said body is in the closed position.

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5. The guard of claim 1, wherein at least a portion of said upper and lower surfaces of said exterior surface are angled to one another when said body is in the open position.
6. The guard of claim 1, wherein said side surfaces of said exterior surface are parallel to one another.
7. The guard of claim 1, wherein said body has an exterior surface that has a generally circular cross section along at least a portion of the length of said body when in the closed position.
8. The guard of claim 1, wherein said body has an exterior surface that has a generally oval cross section along at least a portion of the length of said body when in the open position.
9. The guard of claim 1, wherein said body has an exterior surface that has a generally elliptical cross section along at least a portion of the length of said body when in the open position.
10. The guard of claim 1, wherein said first and second portions of said body cooperatively engage each other along the length of the body when in the closed position.
11. The guard of claim 1, wherein said first and second portions of said body are hinged to one another to rotatably articulate relative to one another.
12. The guard of claim 1, wherein said first and second portions of said body rotatably articulate relative to one another about an axis of rotation that is fixed relative to the mid-longitudinal axis of said guard when moved between the closed position and the open position.
13. The guard of claim 1, further comprising a lock adapted to cooperatively engage said body of said guard when said body is in the closed position to hold said body in the closed position.
14. The guard of claim 13, wherein said lock is a collar adapted to cooperatively engage said body of said guard when said body is in the closed position to hold said body in the closed position.

15. The guard of claim 1, wherein said body has a height in the range of 8-25 mm.
16. The guard of claim 1, wherein said opening defined by said first and second portions of said body has a height in the range of 8-20 mm.
17. The guard of claim 1, in combination with a bone removal device for forming through said guard an implantation space across the disc space.
18. The guard of claim 17, wherein said bone removal device is selected from the group consisting of a drill, a trephine, a reamer, an end mill, a chisel, and a burr.
19. The guard of claim 17, wherein said bone removal device has a height in the range of 8-20 mm.
20. The guard of claim 1, in combination with an implant driver sized in part for passage through said opening for passing an implant through said guard and into the disc space.
21. The guard of claim 1, in combination with a spinal implant adapted to be inserted into the implantation space formed through said guard.
22. The guard of claim 21, wherein said implant comprises at least one of bone and a bone growth promoting material.
23. The guard of claim 22, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.
24. The guard of claim 21, wherein said implant is in combination with a bone growth promoting material.
25. The guard of claim 24, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.
26. The guard of claim 21, wherein said implant comprises at least one of the following materials: metal, titanium, plastic, and ceramic appropriate for implantation in the human body.

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27. The guard of claim 17, wherein said implant is at least in part resorbable.
28. The guard of claim 21, wherein said implant is formed of a porous material.
29. The guard of claim 21, in combination with a chemical substance adapted to inhibit scar formation.
30. The guard of claim 21, in combination with an antimicrobial material.

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EVIDENCE APPENDIX

NONE.

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RELATED PROCEEDINGS APPENDIX

NONE.